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APPLICATION NO.	FILING DATE	FIRST NAMED INVENTOR	ATTORNEY DOCKET NO.	CONFIRMATION NO.
10/517,088	12/06/2004	Jianming Chen	6480P0010US	1147

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EXAMINER	
KISHORE, GOLLAMUDI S	

ART UNIT	PAPER NUMBER
1612	

NOTIFICATION DATE	DELIVERY MODE
11/25/2009	ELECTRONIC

Please find below and/or attached an Office communication concerning this application or proceeding.

The time period for reply, if any, is set in the attached communication.

Notice of the Office communication was sent electronically on above-indicated "Notification Date" to the following e-mail address(es):

pdocket@ericksonlawgroup.com
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Office Action Summary	Application No.	Applicant(s)	
	10/517,088	CHEN ET AL.	
	Examiner	Art Unit	
	GOLLAMUDI S. KISHORE	1612	

-- The MAILING DATE of this communication appears on the cover sheet with the correspondence address --

Period for Reply

A SHORTENED STATUTORY PERIOD FOR REPLY IS SET TO EXPIRE *3* MONTH(S) OR THIRTY (30) DAYS, WHICHEVER IS LONGER, FROM THE MAILING DATE OF THIS COMMUNICATION.

- Extensions of time may be available under the provisions of 37 CFR 1.136(a). In no event, however, may a reply be timely filed after SIX (6) MONTHS from the mailing date of this communication.
- If NO period for reply is specified above, the maximum statutory period will apply and will expire SIX (6) MONTHS from the mailing date of this communication.
- Failure to reply within the set or extended period for reply will, by statute, cause the application to become ABANDONED (35 U.S.C. § 133). Any reply received by the Office later than three months after the mailing date of this communication, even if timely filed, may reduce any earned patent term adjustment. See 37 CFR 1.704(b).

Status

1)☒ Responsive to communication(s) filed on *23 September 2009*.

2a)☒ This action is **FINAL**. 2b)☐ This action is non-final.

3)☐ Since this application is in condition for allowance except for formal matters, prosecution as to the merits is closed in accordance with the practice under *Ex parte Quayle*, 1935 C.D. 11, 453 O.G. 213.

Disposition of Claims

4)☒ Claim(s) *10-22* is/are pending in the application.

4a) Of the above claim(s) _____ is/are withdrawn from consideration.

5)☐ Claim(s) _____ is/are allowed.

6)☒ Claim(s) *10-22* is/are rejected.

7)☐ Claim(s) _____ is/are objected to.

8)☐ Claim(s) _____ are subject to restriction and/or election requirement.

Application Papers

9)☐ The specification is objected to by the Examiner.

10)☐ The drawing(s) filed on _____ is/are: a)☐ accepted or b)☐ objected to by the Examiner.

Applicant may not request that any objection to the drawing(s) be held in abeyance. See 37 CFR 1.85(a).

Replacement drawing sheet(s) including the correction is required if the drawing(s) is objected to. See 37 CFR 1.121(d).

11)☐ The oath or declaration is objected to by the Examiner. Note the attached Office Action or form PTO-152.

Priority under 35 U.S.C. § 119

12)☐ Acknowledgment is made of a claim for foreign priority under 35 U.S.C. § 119(a)-(d) or (f).

a)☐ All b)☐ Some * c)☐ None of:

1.☐ Certified copies of the priority documents have been received.

2.☐ Certified copies of the priority documents have been received in Application No. _____.

3.☐ Copies of the certified copies of the priority documents have been received in this National Stage application from the International Bureau (PCT Rule 17.2(a)).

* See the attached detailed Office action for a list of the certified copies not received.

Attachment(s)

1) ☐ Notice of References Cited (PTO-892)
2) ☐ Notice of Draftsperson's Patent Drawing Review (PTO-948)
3) ☐ Information Disclosure Statement(s) (PTO/SB/08) Paper No(s)/Mail Date _____.
4) ☐ Interview Summary (PTO-413) Paper No(s)/Mail Date. _____ .
5) ☐ Notice of Informal Patent Application
6) ☐ Other: _____.

DETAILED ACTION

The amendment dated 9-23-09 is acknowledged.

Claims included in the prosecution are 10-22.

In view of the cancellation of some claims and amendments, the 112 rejections and the 103 rejection of claims 7 and 9 over Lee, Modi and Garrity are withdrawn.

Claim Rejections - 35 USC § 103

1. The following is a quotation of 35 U.S.C. 103(a) which forms the basis for all obviousness rejections set forth in this Office action:

> (a) A patent may not be obtained though the invention is not identically disclosed or described as set forth in section 102 of this title, if the differences between the subject matter sought to be patented and the prior art are such that the subject matter as a whole would have been obvious at the time the invention was made to a person having ordinary skill in the art to which said subject matter pertains. Patentability shall not be negatived by the manner in which the invention was made.

2. Claims 10-22 are rejected under 35 U.S.C. 103(a) as being unpatentable over Payne (4,744,989) by itself or in combination with Lee (US 2003/0118616) or Keller (6,610,322) or Cole (6,544,531) or Meybeck (5,034,228) by themselves or in combination.

Payne teaches proliposomal formulations and a method of preparation containing biologically active agents. The preparations contain carrier material such as mannitol and sodium chloride. The proliposomal preparations are made by dissolving the phospholipids in an organic solvent and coated on the material (mannitol or sodium chloride). The phospholipids include distearoylphosphatidylcholine, dipalmitoylphosphatidylcholine and dimyristoylphosphatidylcholine (abstract, col. 5, lines

54-67; col. 7, lines 14-44; examples and claims). Although Payne does not specifically teach vitamin A as the active agent, on col. 6, line 1 et seq., states that the biologically active compound employed in the invention may be any compound of biological interest. Therefore, it would have been obvious to one of ordinary skill in the art to use vitamin A as the biologically active agent in Payne with a reasonable expectation of success.

Lee et al disclose liposomal formulations containing lecithin (0011, 0023), Retinol (Vitamin A), 1 % and sorbitol (2 %) (Abstract and Table 4 on page 5). What is lacking in Lee et al is the use of saturated phospholipids such as DSPC or DPPC for the formation of liposomes. What is also lacking in Lee et al is the teaching of the use of sodium chloride.

Keller discloses liposomal preparations containing tretinoin (example 7). Keller further suggests that the liposomes can be lyophilized in the presence of appropriate cryoprotectants (col. 7, lines 30-35).

Cole discloses liposomes containing retinol. The amount of retinol is 0.4 % (Example 1).

Meybeck similarly discloses liposomal compositions containing tretinoin. Meybeck further teaches lyophilizing the composition (Examples 3-7). The amount of tretinoin as seen from example 1 is 4.76 %.

One of ordinary skill in the art would be motivated to use vitamin A in Payne since the references of Lee, Keller, Cole and Meybeck each teach the routine use of vitamin A in either liposomes or proliposomal compositions.

One of ordinary skill in the art would be further motivated to use vitamin A in Payne since the references of Lee, Keller, Cole and Meybeck each teach the routine use of vitamin A in either liposomes or proliposomal compositions.

Applicant's arguments have been fully considered, but are not found to be persuasive. Applicant argues that Payne reference merely discloses a method of preparing liposome precursors which include dissolving a predetermined amount of at least one liposome amphipathic lipid, optionally a biologically active compound, and optionally at least one adjuvant in an organic solvent. The organic solution is then applied to a carrier material. According to applicant, nowhere in Payne is vitamin A disclosed as a biologically active compound, much less disclosed for use in preparation of a vitamin A liposome comprising 0.2-40 % of vitamin A, and 1-80 % of the support substance. Further according to applicant even when combined with other references which Examiner alleges disclose the use of vitamin A, a person having skill in the art would not be motivated to arrive at the claimed range of 0.2-40% of vitamin A, and 1-80% of the support substance in conjunction with the method disclosed in Payne for preparing a liposome, wherein the addition of a biologically active ingredient: is at most, optional. Applicant argues that the claimed ranges in claims 10 and 15 of 0.2-40% of vitamin A, and >80% of the support, substance are technical features which related to the stability of vitamin A, which are not of concern in Payne.

These arguments are not persuasive. First of all, applicant is incorrect in stating that the biologically active compound is optional in Payne. Payne teaches a method of preparation of proliposomal compositions ***which is applicable to a variety of***

biologically active agents. This is clearly evident from col. 1, line 43 through col. 2, line 12; col. 5, lines 22-40; col. 6, lines 56-63; col. 9, lines 3-6). Example 9 clearly teaches the incorporation of a drug. Amphotericin used in this example is a lipophilic drug just as vitamin A. Furthermore, liposomes are known in the art as carriers of drugs and one of ordinary skill in the art would naturally encapsulate active agents within the liposomes irrespective of method by which they are produced because of this fact. With regard to the amounts of the support material and drugs, the examiner points out that instant claims recite broad ranges and the amount ranges are clearly taught by Payne on col. 5, lines 24-53. Therefore, one of ordinary skill in the art would be motivated to use any drug including vitamin A in the method of Payne from the guidance provided with a reasonable expectation of success. Applicant's arguments that even combining with other references, a person having skill in the art would not arrive at instant claimed ranges are not persuasive since the secondary references clearly teach vitamin A amounts which fall within the broad range claimed in instant claims. Furthermore, the amount of a drug also depends on several parameters such as the severity of the disease to be treated, patients age and other factors and therefore, manipulatable parameters. Applicant's arguments that Payne's method differs from instant method in that instant method uses fluidized bed and the phospholipid, cholesterin and drugs are coated on the surface are not persuasive since first of all claim 10 does not recite these conditions and secondly, applicant has not shown any criticality of removing the solvent in a fluidized bed, freeze-drying method and spray drying method. These methods are routinely practiced in the art as evident from Keller, Cole and Meybeck.

3. THIS ACTION IS MADE FINAL. Applicant is reminded of the extension of time policy as set forth in 37 CFR 1.136(a).

A shortened statutory period for reply to this final action is set to expire THREE MONTHS from the mailing date of this action. In the event a first reply is filed within TWO MONTHS of the mailing date of this final action and the advisory action is not mailed until after the end of the THREE-MONTH shortened statutory period, then the shortened statutory period will expire on the date the advisory action is mailed, and any extension fee pursuant to 37 CFR 1.136(a) will be calculated from the mailing date of the advisory action. In no event, however, will the statutory period for reply expire later than SIX MONTHS from the mailing date of this final action.

Any inquiry concerning this communication or earlier communications from the examiner should be directed to GOLLAMUDI S. KISHORE whose telephone number is (571)272-0598. The examiner can normally be reached on 6:30 AM- 4 PM, alternate Friday off.

If attempts to reach the examiner by telephone are unsuccessful, the examiner's supervisor, Krass Frederick can be reached on (571) 272-0580. The fax phone number for the organization where this application or proceeding is assigned is 571-273-8300.

Information regarding the status of an application may be obtained from the Patent Application Information Retrieval (PAIR) system. Status information for published applications may be obtained from either Private PAIR or Public PAIR. Status information for unpublished applications is available through Private PAIR only. For more information about the PAIR system, see http://pair-direct.uspto.gov. Should you have questions on access to the Private PAIR system, contact the Electronic Business Center (EBC) at 866-217-9197 (toll-free). If you would like assistance from a USPTO Customer Service Representative or access to the automated information system, call 800-786-9199 (IN USA OR CANADA) or 571-272-1000.

/Gollamudi S Kishore/
Primary Examiner, Art Unit 1612

GSK